

Melissa Chuderewicz  
**PEPPER HAMILTON LLP**  
Suite 400  
301 Carnegie Center  
Princeton, New Jersey 08543-5276  
(609) 452-0808

*Attorney for Plaintiff*  
*OTSUKA PHARMACEUTICAL CO., LTD.*

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
APOTEX CORP.	)	Civil Action No.:
	)	
and	)	
	)	
APOTEX INC.	)	
	)	
Defendants.	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Apotex Corp. and Apotex Inc. (collectively “Apotex”), alleges as follows:

**THE PARTIES**

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, North York, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

### **NATURE OF THE ACTION**

4. This is an action for infringement of United States Patent No. 7,053,092 (“the ’092 patent”), United States Patent No. 8,642,600 (“the ’600 patent”) and United States Patent No. 8,759,350 (“the ’350 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Apotex Inc.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market a generic pharmaceutical product (“Apotex’s generic product”).

### **JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex

Corp. is registered as drug wholesaler in the State of New Jersey with registration number 5003192. Upon information and belief, Apotex Corp. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc. directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Apotex Inc.'s generic products. Upon information and belief, Apotex Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

**FIRST COUNT FOR PATENT INFRINGEMENT**

9. The U.S. Patent and Trademark Office ("PTO") issued the '092 patent on May 30, 2006, entitled "5-HT<sub>1A</sub> Receptor Subtype Agonist." A copy of the '092 patent is attached as Exhibit A.

10. Otsuka is the owner of the '092 patent by virtue of assignment.

11. The '092 patent expires on January 28, 2022.

12. The '092 patent claims, *inter alia*, methods of treatment comprising administering aripiprazole.

13. Otsuka is the holder of NDA No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the '092 patent for NDA No. 21-713.

14. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify<sup>®</sup>.

15. Upon information and belief, Apotex Inc. filed with the FDA ANDA No. 20-4094, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

16. Upon information and belief, Apotex Inc.'s ANDA No. 20-4094 seeks FDA approval to sell in the United States Apotex Inc.'s generic product.

17. Otsuka received a letter from Apotex Inc. dated September 12, 2014, purporting to include a Notice of Certification for ANDA No. 20-4094 ("Apotex's 20-4094 letter") under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '092 patent.

18. Apotex's 20-4094 letter alleges that the active ingredient in Apotex Inc.'s generic product for which it seeks approval is aripiprazole.

19. Upon information and belief, Apotex Inc.'s generic product will, if approved and marketed, infringe at least one claim of the '092 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the '092 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4094 seeking approval for the commercial marketing of Apotex Inc.'s generic product before the expiration date of the '092 patent.

21. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 20-4094 complained of herein were done with the cooperation, participation, and assistance, and for the benefit, of Apotex Inc. and Apotex Corp.

**SECOND COUNT FOR PATENT INFRINGEMENT**

22. Otsuka realleges, and incorporates in full herein, paragraphs 13-18.

23. The PTO issued the '600 patent on February 4, 2014, entitled "Method of Treating Autism." A copy of the '600 patent is attached as Exhibit B.

24. Otsuka is the owner of the '600 patent by virtue of assignment.

25. The '600 patent expires on July 28, 2022 (including pediatric exclusivity).

26. The '600 patent is directed to and claims, inter alia, methods of treatment comprising administering aripiprazole.

27. Otsuka lists the '600 patent in the Orange Book for NDA No. 21-713.

28. Apotex's 20-4094 letter purports to include a Notice of Certification for ANDA No. 20-4094 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '600 patent.

29. Upon information and belief, Apotex Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '600 patent.

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the '600 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4094 seeking approval to manufacture, use, import, offer to sell and sell Apotex's generic products before the expiration date of the '600 patent.

31. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 20-4094 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Apotex Inc. and Apotex Corp.

**THIRD COUNT FOR PATENT INFRINGEMENT**

32. Otsuka realleges, and incorporates in full herein, paragraphs 13-18.

33. The PTO issued the '350 patent on June 24, 2014, entitled "Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit C.

34. Otsuka is the owner of the '350 patent by virtue of assignment.

35. The '350 patent expires March 2, 2027, subject to any supplemental patent term adjustment.

36. The '350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment comprising administering aripiprazole and serotonin reuptake inhibitors.

37. Otsuka lists the '350 patent in the Orange Book for NDA No. 21-713.

38. Apotex's 20-4094 letter purports to include a Notice of Certification for ANDA No. 20-4094 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '350 patent.

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-4094 seeking approval to manufacture, use, import, offer to sell and sell Apotex's generic products before the expiration date of the '350 patent.

40. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 20-4094 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Apotex Inc. and Apotex Corp.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Apotex Corp. and Apotex Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Apotex has infringed at least one claim of the '092 patent through Apotex Inc.'s submission of ANDA No. 20-4094 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Apotex's generic products in the United States before the expiration of the '092 patent;
- 2) order that the effective date of any approval by the FDA of Apotex's generic product be a date that is not earlier than the expiration of the '092 patent, or such later date as the Court may determine;
- 3) enjoin Apotex from the manufacture, use, import, offer for sale and/or sale of Apotex's generic products until the expiration of the '092 patent, or such later date as the Court may determine;
- 4) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 20-4094 until the expiration of the '092 patent;
- 5) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Apotex has infringed at least one claim of the '600 patent through Apotex Inc.'s submission of ANDA No. 20-4094 to the FDA to obtain approval to manufacture, use, import, offer to sell

and sell Apotex's generic products in the United States before the expiration of the '600 patent;

- 6) order that the effective date of any approval by the FDA of Apotex's generic product be a date that is not earlier than the expiration of the '600 patent, or such later date as the Court may determine;
- 7) enjoin Apotex from the manufacture, use, import, offer for sale and/or sale of Apotex's generic product until the expiration of the '600 patent, or such later date as the Court may determine;
- 8) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 20-4094 until the expiration of the '600 patent;
- 9) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Apotex has infringed at least one claim of the '350 patent through Apotex Inc.'s submission of ANDA No. 20-4094 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Apotex's generic products in the United States before the expiration of the '350 patent;
- 10) order that the effective date of any approval by the FDA of Apotex's generic product be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;
- 11) enjoin Apotex from the manufacture, use, import, offer for sale and/or sale of Apotex's generic product until the expiration of the '350 patent, or such later date as the Court may determine;

- 12) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 20-4094 until the expiration of the '350 patent;
- 13) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 14) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

By: s/ Melissa A. Chuderewicz  
Melissa A. Chuderewicz  
chuderem@pepperlaw.com  
PEPPER HAMILTON LLP  
Suite 400  
301 Carnegie Center  
Princeton, New Jersey 08543  
(609) 452-0808

*Attorney for Plaintiff*  
*OTSUKA PHARMACEUTICAL CO., LTD.*

Of Counsel:

James B. Monroe  
Paul W. Browning  
Denise Main  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT & DUNNER, LLP  
901 New York Avenue, N.W.  
Washington, DC 20001-4413  
(202) 408-4000

Robert L. Baechtold  
John D. Murnane  
FITZPATRICK, CELLA, HARPER &  
SCINTO

1290 Avenue of the Americas  
New York, NY 10104-3800  
(212) 218-2100

Dated: October 27, 2014